

510(k) Summary JUL 26 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of SMDA and 21 CFR 807.92.

1.0 submitter's information

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Contact: Liu Yi
Date of Application: 03/21/2012

2.0 Device information

Trade name: Wi-Fi body scale, model HS5
Common name: Body Analysis scale/ Electronic Body Fat Scale
Classification name: Impedance plethysmograph

3.0 Classification

Production code: MNW- Body Fat Analyzer.
Regulation number: 870.2770
Classification: II
Panel: Cardiovascular

4.0 Predict device information

Manufacturer: Shenzhen Healthcare Electronic Technology Co., Ltd
Device: Body Analysis Scale, Model BG 17
510(k) number: K110928

5.0 Device description

The patient steps on the scale device, where four electrodes are located. The patient must step on the electrodes with bare feet, with normal moisture. Through harmless current stimulation of 500 uA, at 50 kHz, the Wi-Fi body scale calculates the body fat percentage. This calculation is done via the Bioelectrical Impedance Method. The current is passed through the body and the impedance of the body

determines the body fat. The calculation is based upon electrical impedance, height, weight, age, and gender. The calculation is performed via internal software, which uses the variables programmed in by the user. Wi-Fi body scale, model HS5 can be used with an iPod Touch, iPhone or iPad.

6.0 Intended use

Wi-Fi body scale, model HS5 is indicated to measure body weight, estimate body fat, body water percentage, body muscle mass, bones mass, visceral fat rating and daily calorie intake (DCI) using BIA (bioelectrical impedance analysis). This product is for use by generally healthy adults, who are not ill, feverish, have a chronic or acute disease, or a condition that affect the level of hydration such as pregnancy.

7.0 Summary comparing technological characteristics with predicate device

	Wi-Fi body scale, model HS5	Body Analysis Scale, Model BG 17(K110928)	Same or not?
Intended use	Wi-Fi body scale, model HS5 is indicated to measure body weight, estimate body fat, body water percentage, body muscle mass, bones mass, visceral fat rating and daily calorie intake (DCI) using BIA (bioelectrical impedance analysis). This product is for use by generally healthy adults, who are not ill, feverish, have a chronic or acute disease, or a condition that affect the level of hydration such as pregnancy.	Body Analysis Scale, Model BG 17 is indicated to measure body weight, estimate body fat, body water percentage, body muscle mass, bones mass, visceral fat rating and daily calorie intake (DCI) using BIA (bioelectrical impedance analysis). This product is for use by generally healthy adults, who are not ill, feverish, have a chronic or acute disease, or a condition that affect the level of hydration	Same

		such as pregnancy.	
Product Description	Wi-Fi body scale, model HS5 is indicated to measure body weight, estimate body fat, body water percentage, body muscle mass, bones mass, visceral fat rating and daily calorie intake (DCI) using BIA (bioelectrical impedance analysis).	Body Analysis Scale, Model BG 17 is indicated to measure body weight, estimate body fat, body water percentage, body muscle mass, bones mass, visceral fat rating and daily calorie intake (DCI) using BIA (bioelectrical impedance analysis).	Same
Analytical method	BIA (bioelectrical impedance analysis)	BIA (bioelectrical impedance analysis)	Same

8.0 Performance summary

Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1 and EN/IEC 60601-1-2. Clinical testing was used to validate the effectiveness and accuracy of the device. All test results were satisfactory.

9.0 Comparison to the predict device and the conclusion

Our device Wi-Fi body scale, model HS5 is substantially equivalent to the ody Analysis Scale, Model BG 17 whose 510(k) number is K110928.

The two devices are very similar in the intended use, the design principle, the material, the energy source and the applicable standards. Wi-Fi body scale, model HS5 can be used with an iPod Touch, iPhone or iPad.

However, the test in this submission provides demonstration that these small differences do not raise any new questions of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Mr. Liu Yi
President
Andon Health Co., Ltd.
No. 3 Jin Ping Street, Ya' An Road, Nankai District
TIANJIN 300190
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JUL 26 2012

Re: K120896
Trade/Device Name: Wi-Fi body scale, model HS5
Regulation Number: 21 CFR§ 870.2770
Regulation Name: Impedance plethysmograph
Regulatory Class: II
Product Code: MNW
Dated: July 9, 2012
Received: July 9, 2012

Dear Mr. Yi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

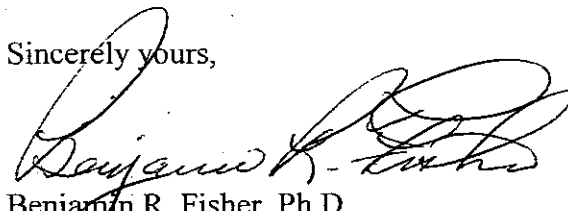
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher", is written over the typed name.

Benjamin R. Fisher, Ph.D.

Director

Division of Reproductive, Gastro-Renal,
and Urological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number : K 120896

Device name: Wi-Fi body scale, model HS5


Indications for use:

Wi-Fi body scale, model HS5 is indicated to measure body weight, estimate body fat, body water percentage, body muscle mass, bones mass, visceral fat rating and daily calorie intake (DCI) using BIA (bioelectrical impedance analysis). This product is for use by generally healthy adults, who are not ill, feverish, have a chronic or acute disease, or a condition that affect the level of hydration such as pregnancy.

Prescription use _____ AND/OR Over-The-Counter Use YES
Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-COUNTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K 120896

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